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Amendment
Attorney Docket No. S63.2B-9515-US01

Amendments To The Claims:

Please cancel claims 17, 22 and 23.

1. (Currently Amended) A balloon for a medical device comprising:
a ~~semi-compliant polymer~~ block copolymer matrix material; and
a plurality of fibers distributed in the matrix material to provide reinforcement thereof,
the fibers being distributed in a selected direction relative to the balloon axis and composed of
material which has a greater tensile strength than the matrix material.
2. (Original) A balloon as in claim 1 wherein the fibers are distributed in the matrix material
helically relative to the balloon axis.
3. (Original) A balloon as in claim 2 wherein said fibers are cores of polymeric material
coextruded with the matrix polymer material.
4. (Original) A balloon as in claim 2 wherein the bulk elongation core polymeric material is
150% or less.
5. (Original) A balloon as in claim 2 wherein the core polymeric material has a bulk elongation
less than the matrix material when oriented in the direction of the longitudinal axis.
6. (Original) A balloon as in claim 1, the balloon having a wall composed of a plurality of
laminate layers, at least one layer of which comprises said polymer matrix material and said
fibers.
7. (Original) A balloon as in claim 6 wherein said laminate layers comprise an alternating series
of fiber-containing and fiber-free layers.
8. (Original) A balloon as in claim 7 having at least 7 of said laminate layers.
9. (Original) A balloon as in claim 6 wherein the fibers are distributed in the matrix material
helically relative to the balloon axis.
10. (Original) A balloon as in claim 9 wherein said fibers are cores of polymeric material
coextruded with the matrix polymer material.
11. (Original) A balloon as in claim 9 wherein said fibers are LCP fibers having a diameter of
from 0.01 to about 10 microns.
12. (Original) A balloon as in claim 6 having a body portion wherein the fibers are oriented
substantially parallel to the longitudinal axis of the balloon.

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13. (Original) A balloon as in claim 12 wherein the fibers are LCP fibers having a diameter of from 0.01 to about 10 microns.
14. (Currently Amended) A balloon for a medical device comprising from 7 to 50 total polymer layers alternating between layers (A) and (B), layer (A) composed of a ~~compliant or semi-compliant polymer~~ block copolymer material and layers ~~layer (B)~~ layer (B) composed of a ~~compliant or semi-compliant~~ block copolymer matrix polymer material and LCP.
15. (Canceled)
16. (Currently Amended) A balloon as in claim 14 wherein the ~~single polymer~~ block copolymer material of layer (A) and the block copolymer matrix polymer material of layer (B) are the same.
17. (Canceled)
18. (Previously Presented) A balloon as in claim 14 wherein the ratio A/B of the total thickness of the two types of layers, (A) and (B) respectively, is from about 5 to about 15.
19. (Original) A balloon as in claim 18 wherein said ratio is from 8 to 10.
20. (Previously Presented) A balloon as in claim 14 wherein in the layers (B) the LCP polymer is present in the blend in an amount of from about 5 to about 25 % by weight.
21. (Original) A balloon as in claim 14, wherein the balloon has a longitudinal axis, at least some of said laminate layers are formed from an extruded blend of a matrix polymer material and an LCP polymer material, and the LCP polymer forming fibers within the matrix polymer with the fibers oriented substantially in a longitudinal or helical direction relative to the balloon axis.
22. (Canceled)
23. (Canceled)
24. (New) The balloon of claim 14 wherein said block copolymer of layer (A) is compliant or semi-compliant and said block copolymer of layer (B) is compliant or semi-compliant.
25. (New) The balloon of claim 14 wherein said block copolymer of layer (A) and said block copolymer of layer (B) are selected from the group consisting of block copolymers comprising polyamide blocks and polyether blocks, block copolymers comprising polyester blocks and polyether blocks, and mixtures thereof.

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Remarks

Rejections

35 U.S.C. §112, first paragraph

Claims 1, 14, 17, 22 and 23 have been rejected under 35 U.S.C. §112, first paragraph, as based on a disclosure which is not enabling. The Office Action asserts that the differentiation between the terms "compliant" and "semi-compliant" is critical or essential to the practice of the invention, but not included is the claim(s) is not enabled by the disclosure.

Claims 1 and 14 have been amended.

Claims 17, 22 and 23 have been canceled.

The Office Action asserts that claims 18-20, 22 and 23 recite the limitations "layer (A) and "layer (B)", and that there is insufficient antecedent basis for these limitations in the claims which depend on parent claim 14.

Claim 14 has been amended. Claims 18-20 depend from claim 14.

Claims 22 and 23 have been canceled.

New claims 24 and 25 have been added, however, which includes both terms "compliant" and "semi-compliant".

Since both compliant and semi-compliant materials are included in the claim, it is irrelevant whether or not the terms overlap. Applicants assert that no clear distinction is required between the terms.

Furthermore, this terminology is commonly employed in the art, and those of ordinary skill understand such terminology. Applicants have included the results of a search illustrating the fact that the terminology is commonly employed.

The disclosure is enabling for both "semi-compliant" and "compliant" polymer materials. See claim 17.

Support for claim 25 is found on page 5 of the specification.

35 U.S.C. §103(a)

Claims 1-7, 9 and 11-13 have been rejected under 35 U.S.C. §103(a) as being

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unpatentable over Rau et al. (previously cited WO 95/18647) in view of Zdrahala (previously cited US 5,248,305), as evidenced by Bland et al. (previously cited US 5,427,842).

The Office Action asserts that regarding claim 1, Rau et al. has a balloon for a medical device (catheter) (column 1, lines 10-15) comprising a plurality of fibers to provide reinforcement (column 14, lines 25-30) wherein the reinforcing fibers may comprise LCP (column 15, lines 1-5). The Office Action asserts that Rau et al. also teach that other thermoplastic materials used to make the balloon may include polyurethane (column 1, lines 15-20).

The Office Action further asserts that Bland et al. teach that the ductile polymer may be a polyurethane or a polyamide (column 4, lines 45-55). Applicants' specification teaches that polyamide belongs to the group of "compliant" or "semi-compliant" polymer (page 10, lines 28-31 and thus the term "ductile overlaps the terms "compliant" and "semi-compliant", and thus, polyurethane is semi-compliant as evidenced by Bland et al.

The Office Action thus concludes that it would have been obvious to one of ordinary skill in the art to have used polyurethane instead of thermoplastic polyimide (column 2, lines 15-20) in order to obtain a balloon with increased compliance.

Applicants have amended claim 1 to recite "a block copolymer matrix material".

Neither Rau et al. nor Bland et al. teach block copolymers.

Zdrahala et al. is directed to catheter tubing, not balloons.

Consequently, claim 1 as amended is not obvious over this combination of references.

Claims 2-7, 9 and 11-13 depend from claim 1 and are patentable over Rau et al. (previously cited WO 95/18647) in view of Zdrahala (previously cited US 5,248,305), as evidenced by Bland et al. (previously cited US 5,427,842).

Applicants respectfully request withdrawal of the rejection of claims 1-7, 9 and 11-13 under 35 U.S.C. §103(a) as being obvious over Rau et al. (previously cited WO 95/18647) in view of Zdrahala (previously cited US 5,248,305), as evidenced by Bland et al. (previously cited US 5,427,842).

Claims 1, 7-8, 14 and 16-23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. in view of Bland et al., as evidenced by Zdrahala.

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Claim 1 has been amended as discussed above. Claims 7-8 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable.

Claim 14 has been amended as well, reciting that the polymer material of layer (A) is a block copolymer and the polymer material of layer (B) is a block copolymer.

Rau et al. teach polyimides.

Bland et al. do not teach block copolymers.

Zdrahala is directed to catheter tubing, not medical balloons.

Applicants assert that claim 14, as amended, is not obvious over this combination of references for the same reasons that claim 1 is not obvious over this combination of references.

Claims 16 and 18-21 depend from claim 14 and are patentable for at least the reasons that claim 14 is patentable.

Claims 17, 22 and 23 have been canceled.

Applicant respectfully request withdrawal of the rejection of claims 1, 7-8, 14 and 16-23 have been rejected under 35 U.s.c. §103(a) as being unpatentable over Rau et al. in view of Bland et al., as evidenced by Zdrahala.

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CONCLUSION

Claims 1-14, 16, 18-21 and 24-25 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be contacted at (952)563-3011, to expedite prosecution of this application.

Respectfully submitted,

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Date: September 22, 2004

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